5/7/01

K003405 510(k) SUMMARY

The Summary of Safety and Effectiveness on the Endoscopic Monopolar Instruments reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	John Niksa, President Highland / Marietta, Inc. 6155 Heisley Road Mentor, Ohio 44060
Telephone	440/354-0957
Facsimile	440/354-6106
Date	May 4, 2001
Name	Endoscopic Monopolar Instruments
Classification	Gynecologic laparoscope and accessories, 21 CFR 884.1720
Predicate:	Primus™ Insulated Forceps, 510(k) K932932
Description	The design description of the Family of Endoscopic Monopolar Instruments is a reusable instrument with push rod contained within a shaft (15 - 45cm) in length. One end of the push rod is attached to ring handles through an external gasket, preventing carbon dioxide from escaping the body cavity through the lumen of the instrument; the other end of the push rod is connected to jaws with various tooth configurations to meet the needs of the surgical procedure. The opening and closing of the handles activates the opening and closing of the jaws, which tooth design configuration, will vary to meet the needs of the surgical procedure.
Intended Use	The Family of Endoscopic Monopolar Instruments is intended for use in general or gynecologic surgical procedures that utilize minimally invasive surgical procedures. The primary function of the insulated forceps (scissors, graspers, dissectors, suturers, and needle drivers) is to provide the surgeon the ability to manipulate tissue, organs or bowels during minimally invasive surgery. The secondary function of the Endoscopic Monopolar Instruments is to provide monopolar electrocautery capability for ablation / coagulation of soft tissue.
Warning:	Do not use any instrument that exhibits insulation degradation. Any damage of the insulation such as dents, scratches, cracking or splitting may allow electric current leakage and cause shock to the patient or doctor. Keep voltage/power as low as possible to achieve the desired effect maximum power should not exceed 120 watts. Please refer to the electro surgical generator and laparoscope labeling for contraindications and any additional warnings or precautions.
Caution:	Federal law (U.S.A.) restricts this device to sale by or on the order of a physician. Do not activate the electro surgical unit simultaneously with the aspiration / irrigation mode as this condition may alter the path of the electrical

K003405 510(k) SUMMARY, continue

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Precaution:	energy away from the target tissue. The user should precautions to ensure that all minimally invasive components including laparoscope, forceps, trocars and sleeves, electrocautery units, cables, and patient grounding plate are compatible and intended for minimally invasive surgery. It is imperative that all intended electro surgical instruments be in contact with or next to the tissue or target prior to activation of the generator to eliminate the possibility of voltage/current seeking an exit through the insulation to the closet "ground". Activate generator only when instrument is in position.
Technological Characteristics	The intended use and technological characteristics of these devices do not vary significantly. The safety and effectiveness of the Endoscopic Monopolar Instruments are comparable to that of the Primus^{tm} Insulated Forceps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2001

Mr. John Niksa
President
Highland / Marietta, Inc.
6155 Heisley Road
MENTOR OH 44060

Re: K003405
Endoscopic Monopolar Forceps (scissors, graspers, suturers, dissectors, and needle drivers)
Dated: February 27, 2001
Received: February 27, 2001
Regulatory Class: II
21 CFR §884.4160/Procode: 85 KNF
21 CFR §878.4400/Procode: 79 GEI

Dear Mr. Niksa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003405

Device Name: Endoscopic Monopolar Instruments

Indications For Use:

The Family of Endoscopic Monopolar Instruments is intended for use in general or gynecologic surgical procedures that utilize minimally invasive surgical procedures. The primary function of the insulated forceps (scissors, graspers, dissectors, suturers, and needle drivers) is to provide the surgeon the ability to manipulate tissue, organs or bowels during minimally invasive surgery. The secondary function of the Endoscopic Monopolar Instruments is to provide monopolar electrocautery capability for ablation / coagulation of soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003405

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)